Biotest Hycon ID Tool

Release 1.0

Instruction Manual (pg. 2)
HYCON ID Software (pg. 11)

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INSTRUCTION MANUAL

HYCON identification and documentation (HYCON ID)

In combination with a RCS High Flow air sampler (item no. 940 216) and a personal computer, this HYCON-ID set facilitates, with the help of barcode information, the wireless collection, storage and documentation of all important data covering airborne bacteria. This way, serious mistakes that may occur when documentation is produced manually i.e. written down by hand, can be avoided, processing is very much accelerated and the use of paper documents is considerably reduced.

The HYCON-ID set consists of the following components:

- 1x Bluetooth adapter (with installation software and instructions)
- 1x Barcode scanner
- 1x Rechargeable batteries
- 1x Battery charger
- 1x CD-Rom with installation programs
  (data transmission program, HYCON-ID analytical program, manual)
- 1x Operation instructions

In addition, the following items are required:
- 1x RCS High Flow air sampler (item no. 940 216)
- 1x Personal computer (with Windows 2000 system)
  Pack 4 or Windows XP professional system
  Pack 2 (operation with other Windows operating systems is possible but was not tested)
  Minimum available hard disk storage: 100 MB
  Minimum working memory: 256 MB
  Screen resolution 1024 x 768
- Biotest agar strips with barcode labels

The use of the following is recommended but not urgently required:

- Additional barcode labels for collection site, users or two further items of information. It is possible to order an additional barcode label printer (with labels and software to generate a data matrix code) (item no. 940365) to produce these barcode labels.

- Barcode scanner with cable (item no. 940 368) for the connection to the USB interface of a personal computer.
With the help of this input device and based on the barcode on the agar strip, any associated data can be swiftly called up in the analytical program. This is important for facilities such as microbiology laboratories who are in charge of the incubation and analysis of the agar strips.

Setting up the RCS High Flow system

Setting up the wireless transmission of collected data on the RCS High Flow air sampler

The RCS High Flow air sampler acts as an interface between the barcode scanner and the personal computer on which the analytical software is installed. It collects information from barcodes, which is transmitted from the barcode scanner to the air sampler via a Bluetooth interface. It adds its own information to the actual collection process (volume, date, time etc.) saving it on an internal memory. Up to one thousand data records can be collected this way. If around 80 percent of the memory has been taken up, the fill level of the memory is displayed as a percentage figure on the screen for three seconds after the device has been switched on. As soon as the memory has been filled to 100 %, the saving of any further new record causes the respective oldest record to be deleted. Therefore, it is recommended to lose no time downloading the saved records on a computer with analytical software. After a successful transmission, the memory can be wiped.

Setting up the wireless transmission of data via Bluetooth

(see also chapter 6.1 of the operating instructions for RCS High Flow)

The RCS High Flow air sampler can either be connected to a barcode scanner from which it receives data or it can connect with a personal computer in order to transmit this data.

Establishing a connection with a scanner:

After turning on the air sampler, you can change from the volume display to the service menu (picture on the left) by pressing the [Menu/On] key. By pressing the Start/Stop key, you move to the icon with the ‘radio signal’, which will then have a dark background.

After choosing the appropriate symbol in the service menu, you press the [Menu/On] key to get to the Bluetooth data transmission menu.

Selection of Bluetooth data transmission

Data transmission to the scanner

To carry out wireless data transmission from the HYCON-ID set (cat.no. 940 360) with the help of the scanner, the field under the disk symbol must indicate "ON". If it is turned to "OFF" it needs to be switched to “ON” by pressing the [+] and [-] keys.

Getting to the menu by pressing the [Menu/On] key "Selection of code type".

The code can consist of two parts: a so-called "identifier" part and the actual information part. The identifier helps the RCS High Flow air sampler to identify the type of information. For example, the identifier [LOC] indicates that the subsequent information refers to the sampling location.
Without an identifier, the information is simply saved without allocation i.e. on call, which may, due to possible mix-ups, lead to incorrect entries. Therefore, the HYCON-ID system is designed to be used with identifiers. However, if somebody wants to use his own codes whose identifiers are different from the HYCON-ID or which have no identifier at all, it is also possible to input another code.

There are three types of code entry:
[ON] = all codes are recognised and correctly allocated due to identifiers. There is no need to stick to a particular order when scanning in information.

ON=Barcodes with identifiers **OFF=Barcodes without identifiers** **PRE = Barcodes with pre-scanned identifiers**

[OFF] = no codes have identifiers. Therefore, it is necessary to adhere to the scanning order.

[PRE] = the scanning process consists of two parts: first, the identifier needs to be scanned in from the enclosed table or the attached code cards. This needs to be followed by scanning in the code with the relevant information. This way, even codes without identifiers can be correctly allocated. However, the correctness of any information that is subsequently scanned in cannot be ensured.

On the RCS High Flow system, one can choose these settings using the [+]- and [-] keys.
By pressing the [Menu/On] key, you return to the service menu and save the chosen setting.

If this setting is activated, the disk symbol is always on display. It indicates that the sampling process starts with the search for a scanner to obtain specifically selected sampling information. Only when this information has been fully transmitted to the air sampler (identifiable by a black disk symbol), the actual sampling process can begin [START/STOP].

Establishing a connection with a personal computer

First of all, the Bluetooth adapter included with the HYCON ID set needs to be installed on the PC together with the software provided. To do this, please follow the respective instructions in the operation manual. In particular, after the system has been rebooted, it is important to ensure that a Bluetooth symbol appears at the bottom left hand corner of the desktop. If this is not the case, the program needs to be restarted (via "START/Programs/Bluetooth). Ensure that a port larger than COM 4 has been chosen (the first COM-Ports are for actual serial interfaces). The Bluetooth adapter must only be inserted into an USB port when the program asks for it. In addition, the data transmission software (RCS 2 PC) together with the analytical software (Hycon ID) that are included on the CD-Rom need to have been successfully installed (see instructions further down). Prior to the data transmission from the RCS High Flow sampler, the PC must have been switched on and the Bluetooth interface must have been activated.

After switching on the air sampler, you move from volume display to the service menu by pressing the [Menu/On] key.

By pressing the [Start/Stop] key once, you get to the Bluetooth data transmission menu. You confirm your choice by pressing the [Menu/On] key.

Selection of Bluetooth data transmission

Data transmission to the PC

In order to establish a wireless data transmission to a personal computer you need to select the PC symbol. To do this you need to use the [START/STOP] key. The PC field has a dark background.

By pressing the [MENU/ON] key you start the data transmission. On the screen display, you will see the number of data records that are being transmitted to the personal computer. If there is no data transmission or if the data transmission is faulty, an error message appears. This does not affect the data records, which will be preserved. This process can be terminated with the help of the [MENU/ON] key and repeated at a later time.

Selection of sampling data (HYCON-ID)
(see also chapter 6.2 of the RCS High Flow operating manual)

You use the HYCON-ID sub-menu to determine which data is going to be recorded via barcodes and transmitted to the RCS High Flow system prior to the sampling process.

After choosing the respective symbol on the service menu, you enter the HYCON-ID menu by pressing the [Menu/On] key.

Selection of HYCON-ID

HYCON-ID Menu

Information covering the following topics can be chosen:
[AGAR] = all information on the used agar strip complete with
product number, batch and expiry date.
In addition, the barcode features an individual sample number.
This information is obligatory and cannot be deactivated.

[USER] = information on the user
[LOC] = information on the sampling location
[DF1] = Free information 1
[DF2] = Free information 2

Selecting information option

Selecting information

Activating information

With the help of the [+] and [-] keys you can move to the desired fields and select your options using the [START{STOP] key. Using the [+] and [-] keys you can change the suffix in front of the fields from "-" to "+". "+" indicates that this information needs to be scanned in prior to the scanning process.

By pressing the [Menu/On] key, you return to the service menu.

Scanner

Recharging the batteries

Prior to use, the rechargeable battery needs to be charged using the charging device provided. For this purpose, the rechargeable battery must be placed into the underside of the scanner (where an empty battery housing is located). Then you insert the scanner complete with battery backwards into the opening of the charging point.
Charging starts immediately and is finished after approximately three hours.
It is recommend to always keep the scanner in the charging point because it is easiest to scan with the device when it is fully charged.
The rechargeable battery can be charged around one thousand times: afterwards it needs to be replaced with a new battery. Defective and used rechargeable batteries need to be disposed of in accordance with local regulations. Do not add to your household waste. Do not throw into an open fire!

Disinfecting the scanner

The scanner can be wiped with any common neutral disinfectant. Treating it with gas or submerging it in a disinfectant solution is not recommended. There is no warranty if, due to incorrect use, a disinfectant has entered and destroyed the scanner.

Scanning

If the RCS High Flow sampler requests an input, the barcode scanner is placed on the respective barcode at a distance of around 5 to 10 cm and the right hand key is pressed to read in the information. A red laser beam helps the device to focus. As long as the key is pressed down, the laser beam can be adjusted directly onto the label. It is important to hold the device at a slight angle to the data matrix code in order to facilitate error-free scanning (this way, there are fewer reflections of the labelling material).
The scanner reads all types of barcodes and data matrix codes.

Starting the sampling process with barcode scanning

The disk symbol in the display always indicates that the sampling process does not start until all the information that has been stipulated in the "HYCON-ID" menu has been transmitted to the RCS High Flow system with the help of the scanner (see above).
If codes with identifiers have been chosen (ON-Mode), the display shows all selected items of information. Recognition of the code is followed by an acoustic signal after which the displayed information is ticked off as having been confirmed. The order in which the information is entered is random.

If codes without identifiers have been chosen (OFF-Mode), the display screen only shows the information that is to be scanned in. In this context, it is essential that the correct code is scanned in. In this setting, the device cannot identify whether the information is correct. As soon as the information has been transmitted, the next information request appears on the display.
If, prior to reading in a code without identifier, an identifier is to be scanned in (PRE-Mode), the process consists of two parts: first, you read in the relevant identifier and then you scan in the appropriate information taking care to indicate that the subsequent information belongs to the identifier because the device itself does not recognise this connection.

The identifier data matrix codes have the following format:

= Identifier for the sampling location. Subsequently, up to 82 characters can be scanned in

[LOC]

= Identifier for the user. Subsequently, up to 82 characters can be scanned in

[PID]

= Identifier for own information. Subsequently, up to 82 characters can be scanned in

[DF1]

= Identifier for own information. Subsequently, up to 82 characters can be scanned in

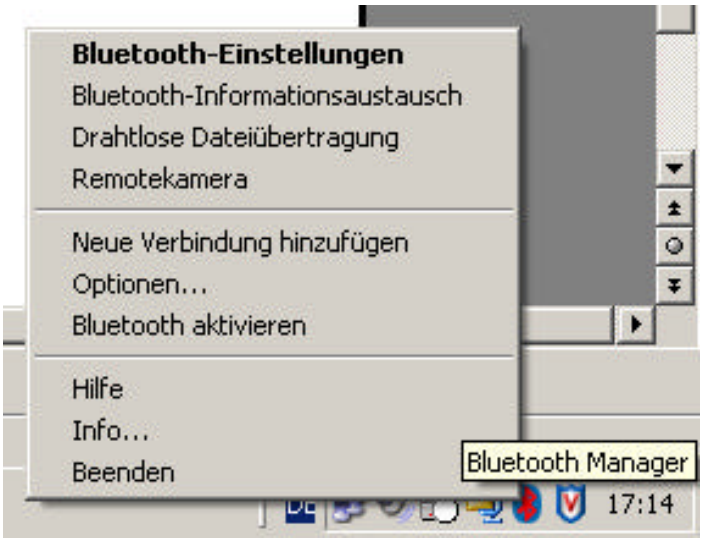
[DF2]

As soon as all the data has been scanned in, the disk symbol on the display has a dark background. Now, the sampling process can be started.

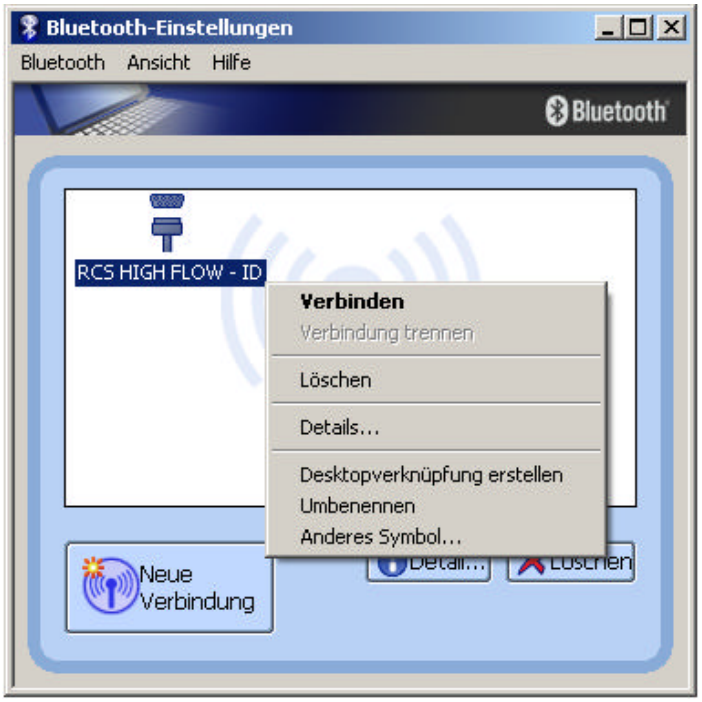
Data transmission on a personal computer and scanning data into the HYCON-ID software

First, you establish a Bluetooth connection with the personal computer (as described above)

Start the personal computer and, in the Bluetooth Manager (after installation, the icon appears at the bottom right hand corner of the task bar), open the "Bluetooth settings" dialog box (right hand mouse click on the "Bluetooth Manager" icon).

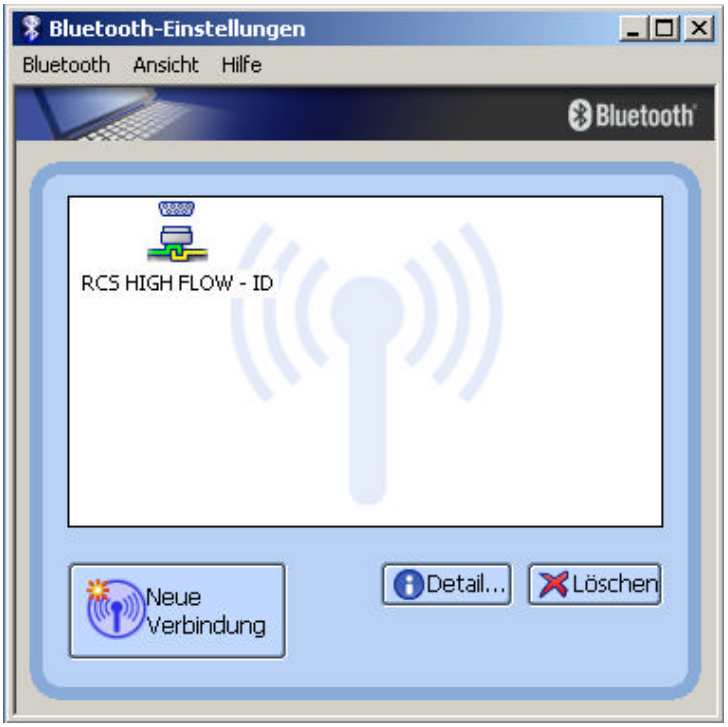


Icon of the Bluetooth manager



Establishing a connection with the RCS device

Establish a connection with the RCS device by clicking on the "Verbinden" field in the "Bluetooth-Einstellungen" dialog window. ATTENTION: a connection can only be established if the data transmission to the PC (see above) has been activated and the RCS device "is sending". A small symbol showing two hands (green and yellow) indicates a successful connection.



Interlinked “hands” symbolise the connection between the RCS device and the computer.

Now you can start the "RCS2PC" transmission software and read in the data from the device into the PC. Make sure that the connection is maintained. If necessary, repeat the connection process. Follow the instructions below regarding the scanning of data records and/or the calling up of samples, their processing and printing.

Biotest Hycon ID Tool

release 1.0

Manual HYCON ID Software

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1 Welcome

1.1 What is the Biotest Hycon ID Tool?

In combination with the RCS High Flow (item no. 040 216),the HYCON-ID Tool is used for the wireless transmission, collection, archiving and printing of data covering the entire process of airborne bacteria collection. It is used wherever error-free documentation of data on a microbiological collection process is prescribed or necessary in accordance with the microbiological monitoring of clean rooms.
This data includes information on the collection place, the user, the collection medium, the collection device as well as the collection process itself (sample volume, date/time of the collection, specific information) as well as the evaluation and interpretation of the microbiological analysis.
The scope of access and the user options of the HYCON-ID depend on the access authorisations of the individual user, which are assigned by an administrator.

1.2 Installation

Log into your system as administrator. Place the CD into the CD drive of your PC. If the installation does not start automatically (AutoPlay of CD) start the programme BSI.exe of the CD. The following screen is displayed:

Select the entry Install Hycon ID Software and confirm it by <Start>.

Installation runs in two steps. First, the database server is installed, and then the software itself. The "InstallShield Wizard" will guide you through the installation step by step.

1.2.1 Installation of Database server

First, select the installation language:

(Choose language used during installation)

Then, installations starts with the Firebird "welcome" screen:

Setup - Firebird Database Server 2.0
Welcome to the Firebird Database Server 2.0 Setup Wizard
This will install Firebird 2.0.0 on your computer.
It is recommended that you close all other applications before continuing.
Click Next to continue, or Cancel to exit Setup.
Next >
Cancel

Click <Next>

→ The license agreement is displayed. Select " I accept... ". Only then will you be able to click <Next>.

→ Information on the installed data is displayed, this information can be found in the file readme.txt in the installation folder of the database server. Click <Next>

→ Proposal of the installation folder for the database server. Please follow the proposal and simply click on <Next>

→ An options menu is displayed. As before, you should not change the options but continue with <Next>.

There are two additional screens to confirm with <Next> without changing any options. Finally, an overview of the settings is displayed. This time, click <Install>.

→ Another information is displayed. Continue with <Next>.

Finally, installation takes place. Finish this first part of installation with <Finish>.

1.2.2 Installation of the program

Now, the welcome window of the Hycon ID Tool is displayed:

Biotest Hycon ID 1.0 - InstallShield Wizard
Welcome to the InstallShield Wizard for Biotest Hycon ID 1.0
The InstallShield(R) Wizard will install Biotest Hycon ID 1.0 on your computer. To continue, click Next.
WARNING: This program is protected by copyright law and international treaties.
< Back
Next >
Cancel

Please click on <Next>

→ The license agreement is displayed. Select " I accept... ". Only then will you be able to click <Next>.

→ Information on the installed data is displayed, this information can be found in the file **readme.txt** in the installation folder of the Hycon ID Tool. Click <Next>

→ PC user und company is displayed. Change if necessary and click <Next>.

→ Proposal of the DestName
The standard subdirectory is C:\Program Files\Biotest\BHIDxxxx\. (xxxx = current version number).By choosing "Change" you can alter the DestName. This window can be used to perform changes or you confirm it with <OK> .

Overview of the settings prior to final installation
Confirm with "Install" → the installation will be carried out

Finally, this message will appear:

Biotest Hycon ID 1.0 - InstallShield Wizard
InstallShield Wizard Completed
The InstallShield Wizard has successfully installed Biotest Hycon ID 1.0. Click Finish to exit the wizard.
< Back
Finish
Cancel

Confirm by clicking <Finish>.

After the installation of the software has been completed, the desktop and the program start menu will feature the corresponding "Biotest HYCON ID" entry.

1.3 System requirements

Computer:

- Operating system Windows 2000 (Service Pack 4) or Windows XP Professional Service Pack 2 (Maybe the software would run with other operating systems, but this is not validated)
- Minimal free disk storage: 100 MB
- Minimal main storage: 256 MB
- Screen resolution 1024 x 768

Note:

The option "Big fonts" must not be selected!

Note:

If your personal computer systems does not meet the system requirements, mistakes, long waiting times and potential programme crashes can be the consequence!

1.4 Features of the software

The Biotest Hycon ID Tool features the following functions:

	Module
1	Import Hycon ID data from data files, e.g. generated by "RCS2PC"
2	Enter and show results
3	Release results
4	Print results
5	Delete results
6	Export data (in preparation)
7	Data table view of all results
8	Working with different databases
9	Archive function
10	Validated 21 CFR Part 11 compliant software
11	User management
12	User definable settings for results, comments, printouts...
13	Logging of all relevant actions

2 First Steps

2.1 UserManager

According to 21 DFR Part 11, it must be clearly traceable at any time which operator performed a specific action. This is why the Biotest Hycon ID Tool features the user management function which has proven valuable in the Biotest HLA Typing Software.

The software distinguishes between the Administrator, (who administers the users) and the Users, who are authorized to create the reports.

The administrator assigns the user names and determines which requirements a password must fulfill. He defines the rights for each user. An example: The confidence principle can be ensured by defining the rights for the evaluation and release. However, the administrator himself is not authorized to perform typing assays or release reports.

The user can change his password, but has no further access to the User Management feature. He can, however, carry out all laboratory tasks within the scope of his authorization (examples: administer, type or release lots or print reports).

When leaving his work station, the user can log out with a mouse click without closing the program.

While using the user management, the following prompts may be displayed:

Do you really want to delete the user?
This appears if a user is accidentally about to be deleted from the list.

Password does not meet the criteria.
The password entered does not match the password criteria established by the system administrator.

Password not confirmed!
The repeated password is incorrect.

User name already present!
Attempt to enter a new user whose name already exists.

Password expired! Please enter a new password.
This appears if the password has expired according to the criteria established by the system administrator.

More than 3 failed attempts! Please inform the system administrator.
The system administrator has allowed a maximum of 3 failed attempts to enter a password. This limit has been exceeded.

User language not selected.
Each user needs to enter his dialog language.

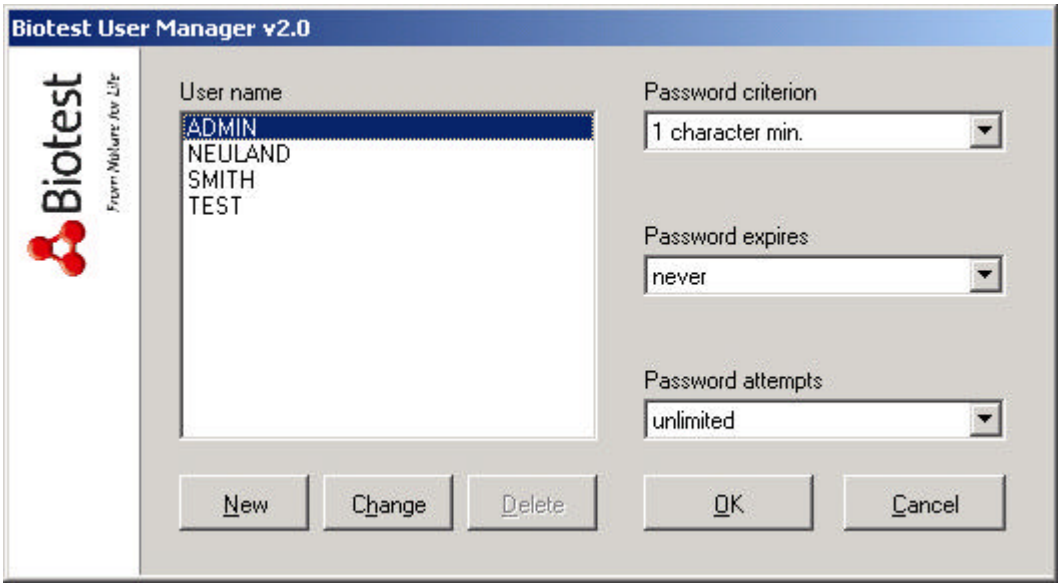
2.1.1 The Administrator

The administrator assigns the user names and determines which requirements a password must fulfill. He defines the rights for each user. An example: The confidence principle can be ensured by defining the rights for the evaluation and release. However, the administrator himself is not authorized to perform typing assays or release reports.

After logging in, the administrator has access to the user management:

The password for the first log-in is ADMIN - admin. The administrator should change the password thereafter.

→ The user management dialog is displayed:



New: A new user is created → see User Management

Change: This is where the administrator can change his password.

Delete: The administrator cannot be deleted!

General settings for all users are made in the right column.

Password criterion: This is where you define how many characters a password must have and whether it must include digits.

Password expires: After a defined amount of time a new password must be entered upon logging in.

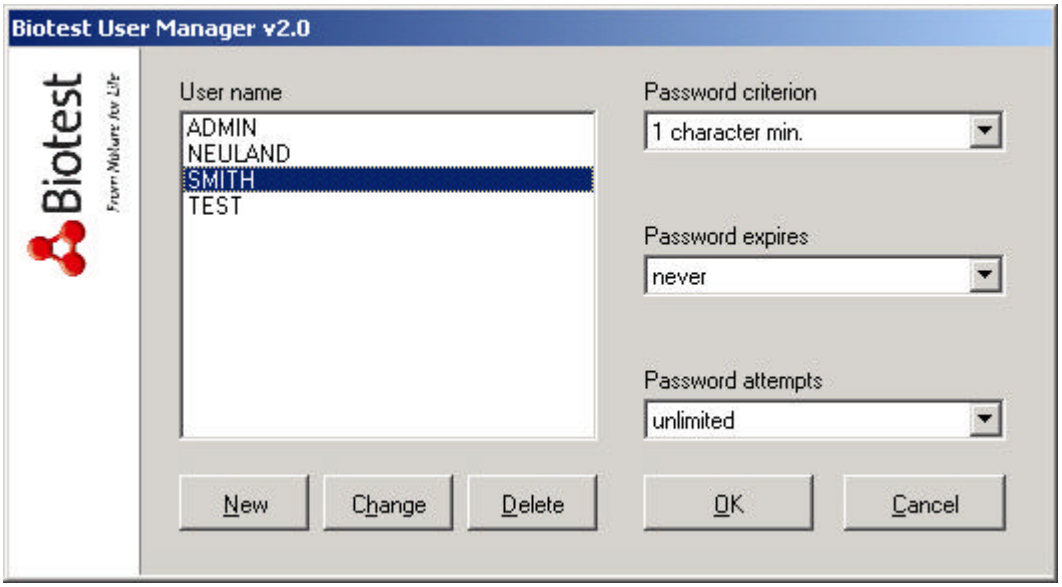
Password attempts: If the defined number of attempts is exceeded, the user can no longer log in and must see the administrator. (Are you the administrator? And you forgot your password? Please contact Biotest's Technical Support!)

2.1.2 User Management

The user can change his password, but has no further access to the User Management feature. He can, however, carry out all tasks within the scope of his authorization (examples: import instrument data, enter results, print or release results).

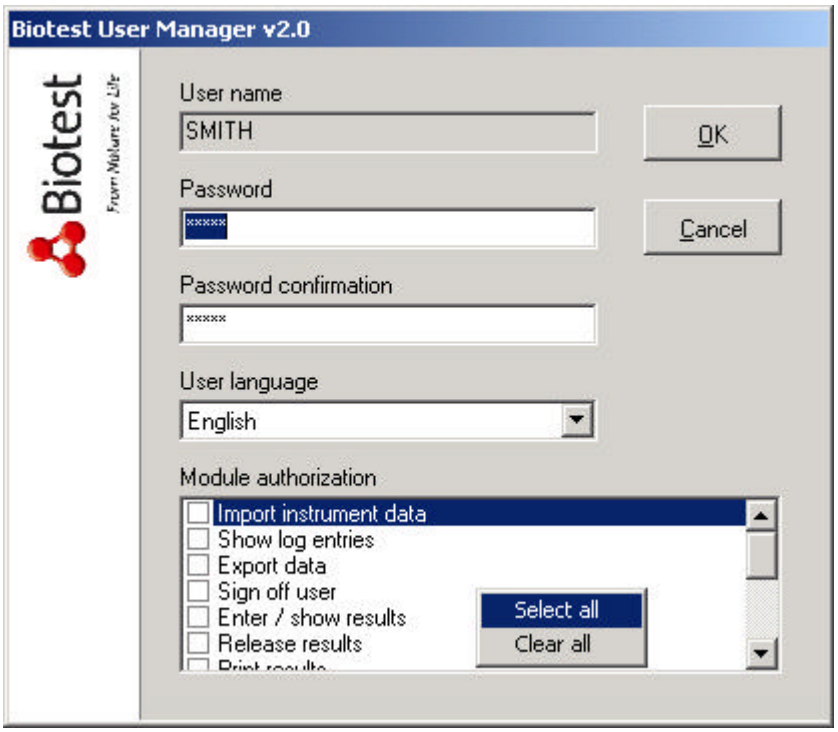
User management is the administrator's task, he is the only one who has access to this feature.

Clicking on <User manager> displays the user management dialog:



General settings are made in the window to the right of the user list. They are described in the chapter The Administrator.

Click on <New> to create a new user:



User name:

The user must enter this name during login. It should therefore be easy to memorize and not be too long.

Password:

When creating a new user, the user name in lower-case letters should be used as the password. The user is then to change his password upon his first log-in.

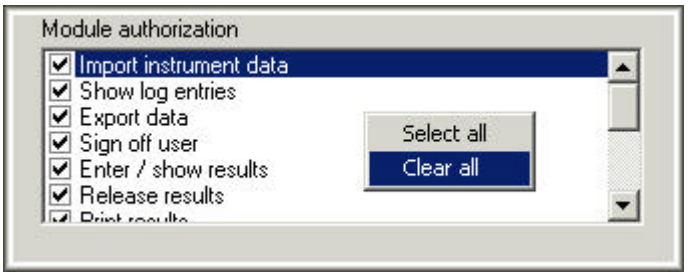
User language:

Please define for each user the language in which he works (currently German or English).

Module authorization:

User rights may also be granted only for certain modules of the software. In order to ensure the confidence principle, the rights for typing and the rights for results release may be granted to different users.

By clicking the right mouse button you can activate a context menu to select or deselect all modules at the same time:



Click on <OK> to save the user data.

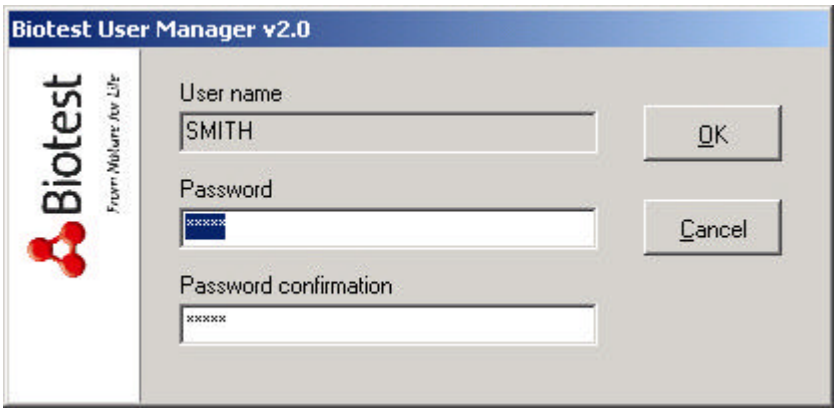
2.1.3 User Log-in /log-out

When leaving his work station, the user can log out with a mouse click without closing the program: just click on the sad face !

The new user clicks on the smiley face : The log-in screen is displayed.

Enter your password, click on <OK> and start working!

After entering the user name and the password, you can change your password (for example because it has expired). Do not click on <OK>, but on <Change password>. The following window will be displayed and allows you to enter your new password:



Click on <OK> to get to the Software.

Forgot your password? See your administrator for help!

2.2 Settings

There are user-specific default options, which cannot be set during installation. However, they are necessary in order to work with the software. Therefore, they should be entered directly after installation.

Call up via **Options - Settings** or directly via

You will find these buttons on each property tab:

Exit settings without saving changes

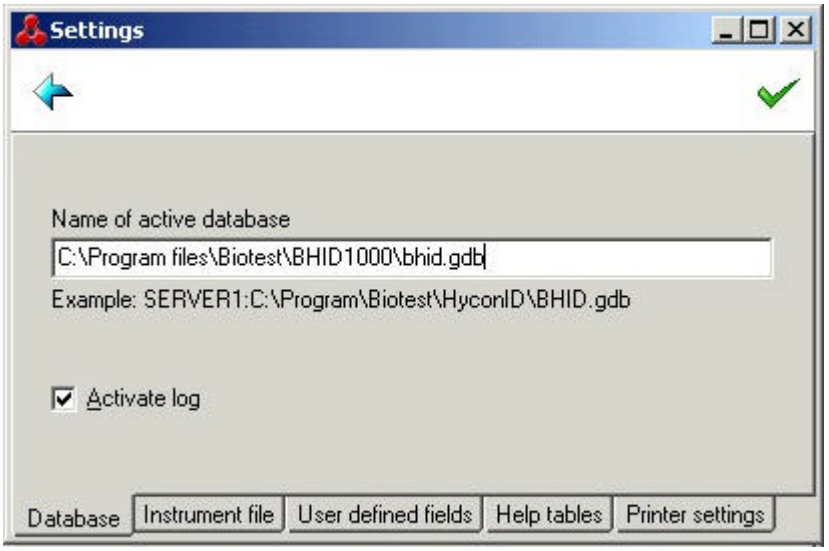
Save changes

2.2.1 Database

The standard path is entered during installation. Here, it can be changed if necessary, for example in order to have access to a specific Archive .

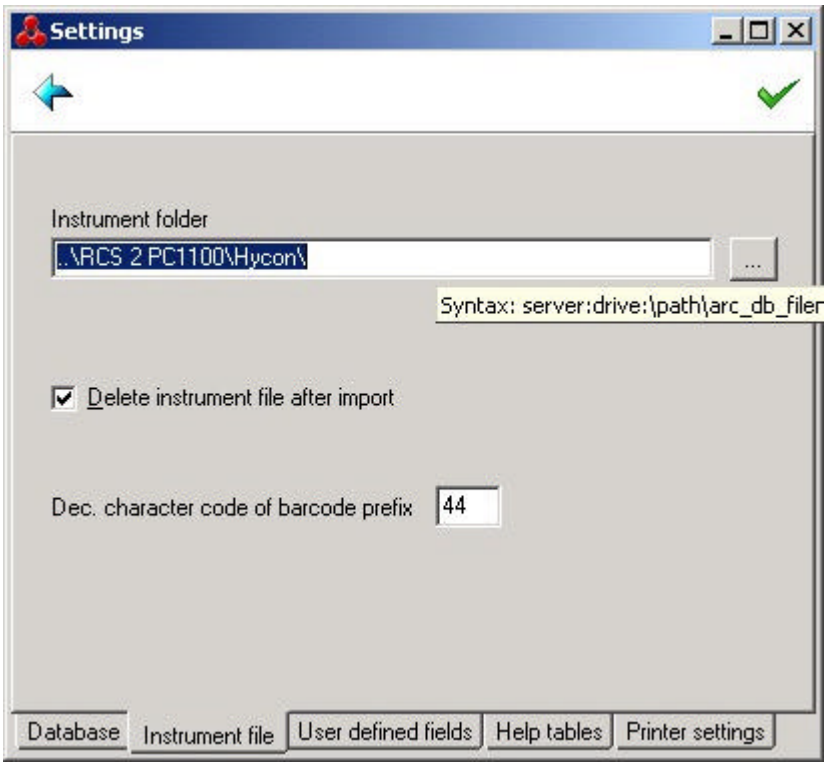
By default, the site log (audit trail) is deactivated. All transactions are recorded in the site log. This way one can check at any time which user carried out which actions.

If you need to comply with 21 CFR Part 11, the audit trail needs to be activated. To do this, click on the check mark:



2.2.2 Instrument data file

This is where you enter the location of the files that are read from the Hycon ID device. The **Hycon** folder has been entered as the default value in the installation directory of the RCS2PC-software. This is where the data of the sampler of airborne bacteria is filed using the hycon*.txt format.



After the import

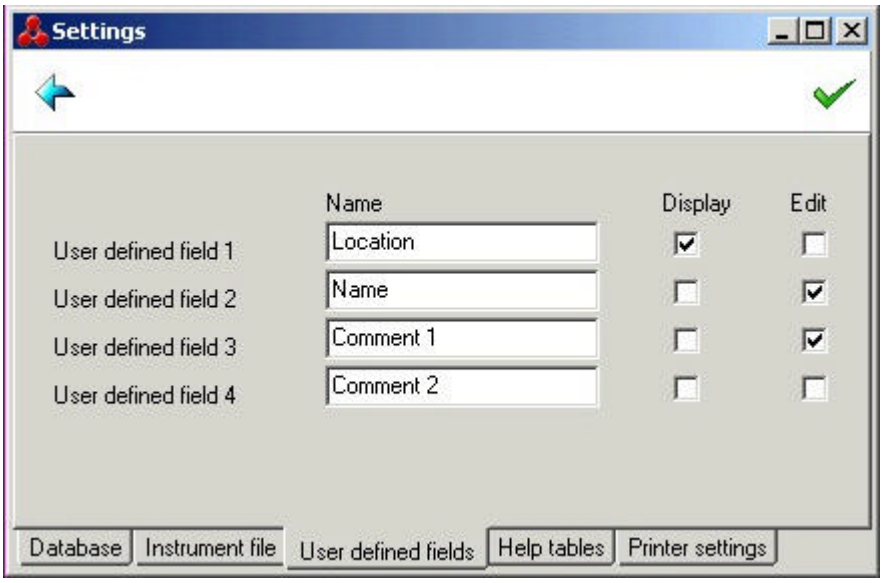
"Delete instrument file after import" is activated as default value. This ensures that instrument data files are not input twice.

Character code for bar code reader

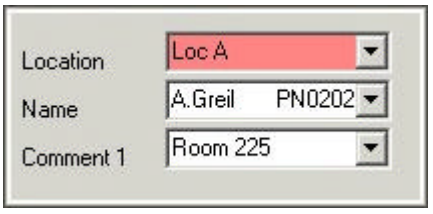
This field is important if you use a bar code scanner. Apart from the identifier, other data is input via the bar code scanner. This would lead to incorrect information appearing in the "identifier" field. Therefore, if the identifier of a sample is input with a bar code scanner, the programme must be informed of this. This is done via an additional character that is sent by the bar code scanner at the beginning. By default, this character is a comma (ASCII-character 44). If your scanner needs to be programmed in a different way, the respective ASCII-Code can be entered here.

2.2.3 User defined fields

This is where the fields are defined, which are located in the middle upper section of the ”results" window.



This setting produces the following picture when a sample is called up:



Four user-defined fields are available, which are configured as follows:

Name The name appears to the left of the field as description.

Display If, for example, during sampling, the location is recorded as well, this information is input together with the instrument data. This means that the location appears in the first user-defined field and it should be made impossible to change it again. This is why here the "display" option is chosen.

Note:

A field where data is only displayed but cannot be changed, has a pink background.

Edit These fields can be used to enter additional information that was not recorded during the sampling, such as the name of the sampler or a keyword regarding the location of the sampling.

Note:

It is possible to specify and save comments for an 'entry' field in order to ensure that these do not need to be entered repeatedly by hand each time. Any comments that are saved in the Help tables can be called up by clicking on the arrow .

It is also always possible to enter random comments.

No check mark Four fields are available. Nevertheless, if certain fields are not required, both check marks relating to the unnecessary fields are removed. In the above example, the "user defined field 4" is therefore not displayed.

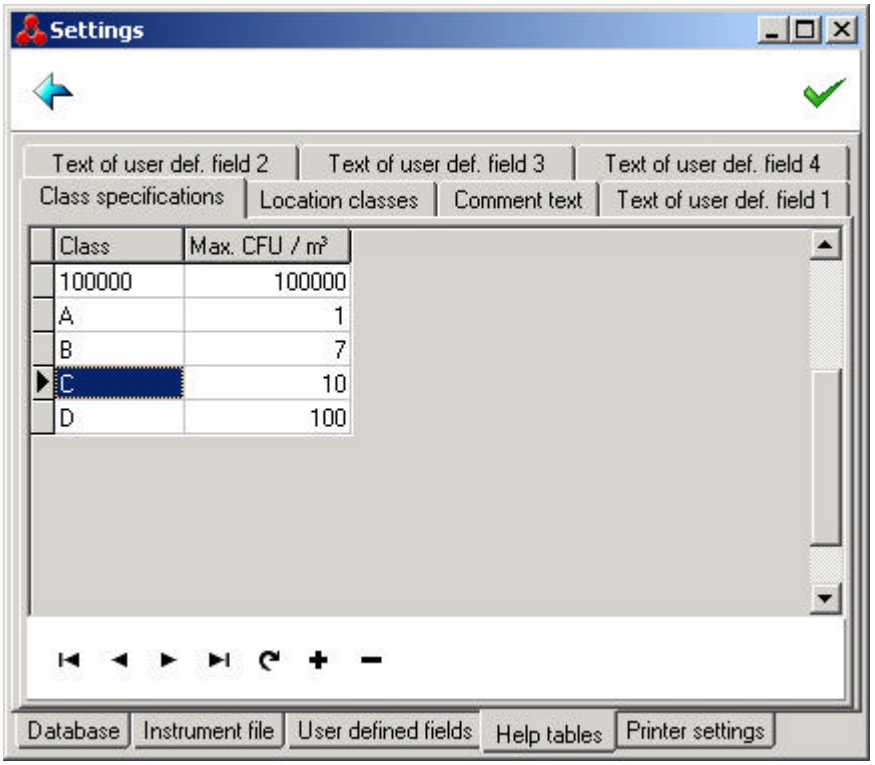
2.2.4 Help tables

As to the help tables, there is a database navigation bar below the tables:

This is used to administer table entries:

- The first table entry is displayed
- The previous entry is displayed
- The next entry is displayed
- The last entry is displayed
- The table is newly sorted
- Add another line
- Delete entry

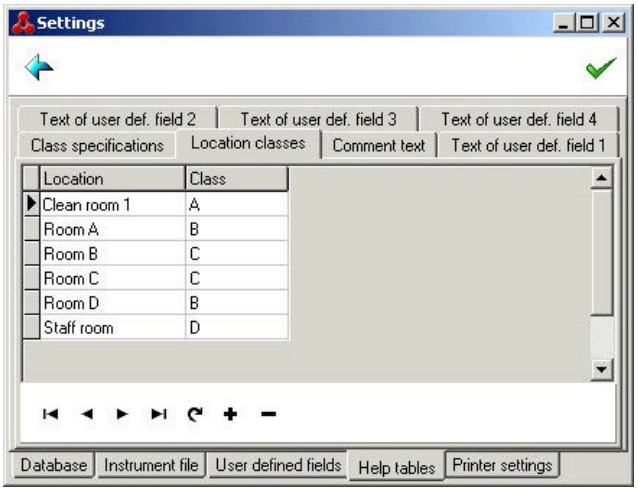
2.2.4.1 Clean room categories



The maximum number of CFU/m³ for clean room categories A to D in accordance with EU directives has already been specified and saved. If you use your own classification, it can be entered here. This setting will only have an effect in combination with the "site categories" table.

2.2.4.2 Location classes

This is where information about the rooms used for the sampling and the specifications that these rooms need to comply with is entered.

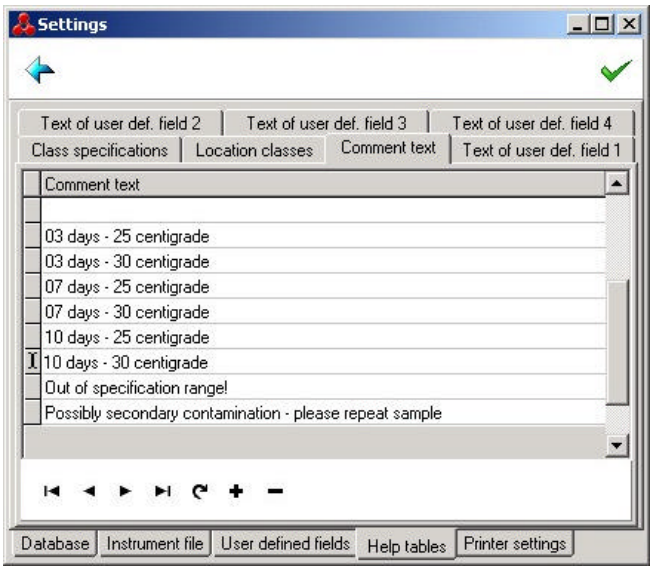


Note:

When the limit for a specific room category has been exceeded, this will be clearly indicated!

2.2.4.3 Text used for comments

During the microbiological analysis of the samples, the same comments such as a statement on incubation conditions are required repeatedly. If these comments are specified and saved here, they can be inserted during the evaluation via a list of options. This will ensure that the same processes are described in a standardised way.



Note:

At any time, you have the option of adding to the comments or of entering

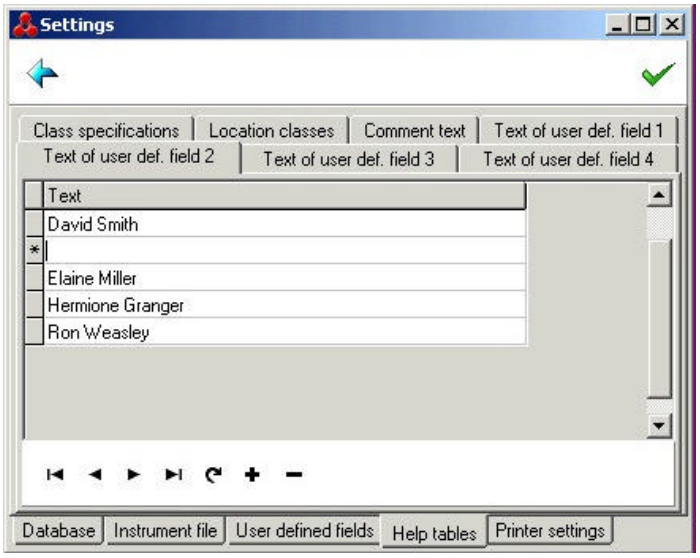
your own comments.

2.2.4.4 Text used for user-defined fields 1- 4

The types of text specified here depend on the default settings in the "User defined fields" section.

It is here where, for example, it was determined that the sampling location is displayed in field 1. The check mark in "display" means that this information is read out from the device. Therefore, there is no need to specify texts for field 1.

Field 2 is to be used to enter the person who has extracted the sample. Therefore, as the "text user-defined field 2" a list of users is specified who, at a later point, can be selected from the option menu:



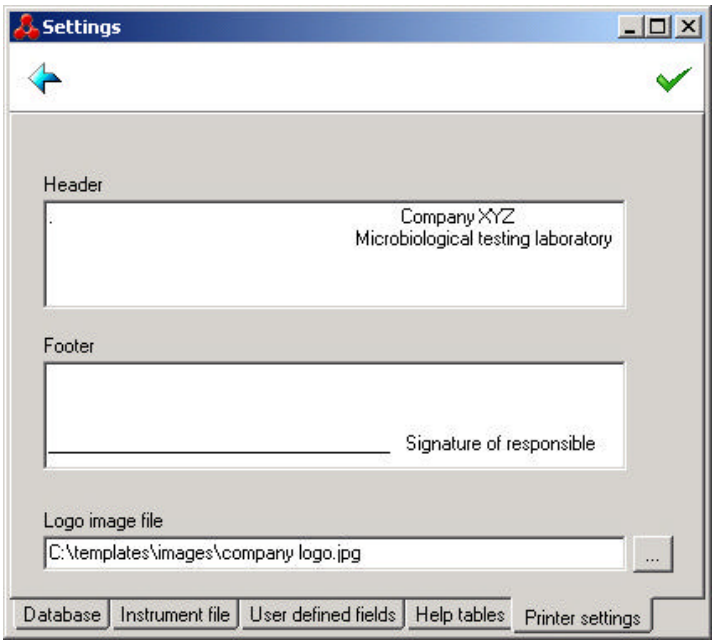
In the same way, standardised entries can be specified for fields 3 and 4.

2.2.5 Printer settings

Here, you determine what the header and footer of a print-out are going to look like.

Four header and four footer lines are available for this purpose.

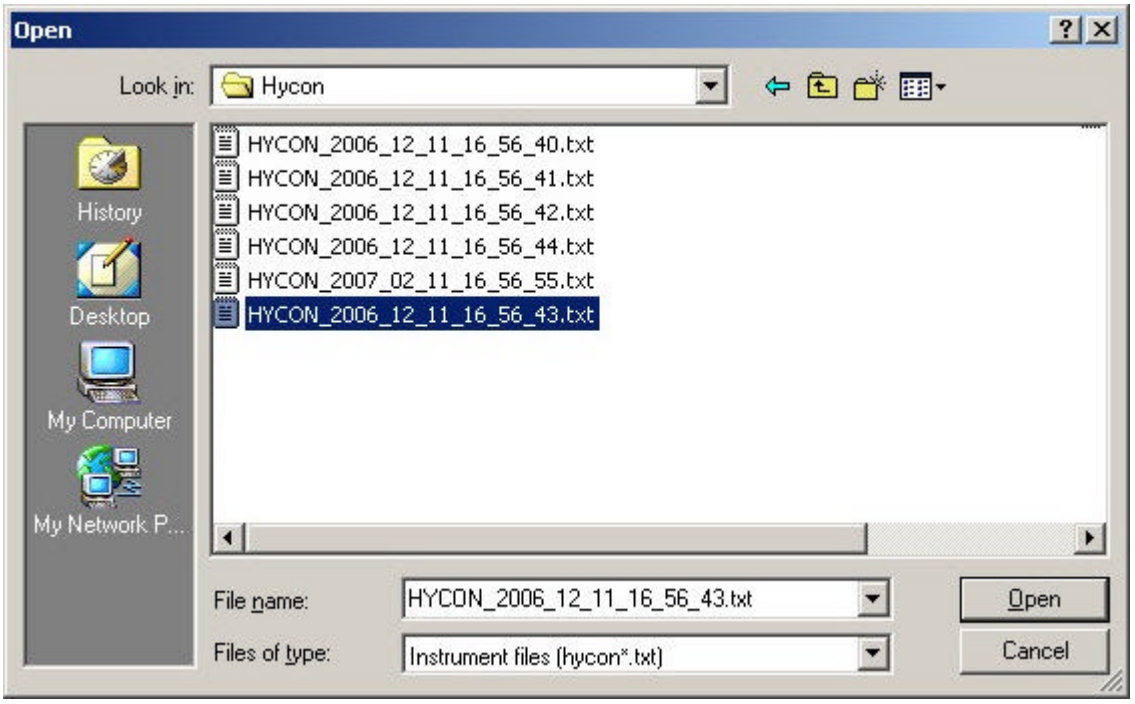
In addition, the logo of the institute can be inserted. This will appear in the top right corner of the print-out.



3 Working with the software

3.1 Import instrument data

First of all, the instrument data is input. This requires a click on or on **file - import instrument data**. The well-known Windows open dialog appears and the folder that has been entered as the "instrument data file folder" in settings is opened:

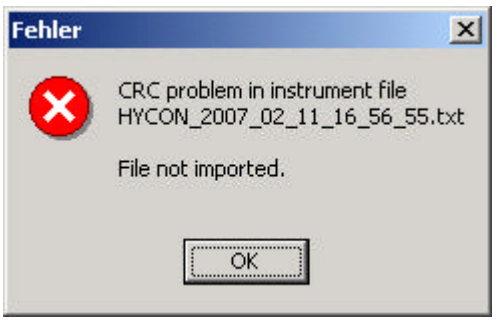


Mark one or several files and click on <Open>. The files are imported and you receive the following message:

You can check the imported data in "view table".

Notes:

If the file is faulty and could therefore not be input, the following error message is displayed:



In **settings**, you can specify that the data is to be deleted after it has been

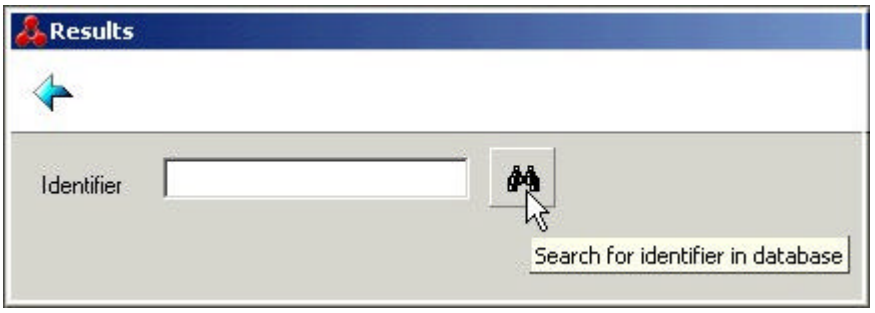
imported.

3.2 Recording results

3.2.1 Calling up sample

To record the results you need to call up the sample from the database. The fastest way to do this is via the identifier.

Call-up via **database - enter/show results** or via .
→ The following screen appears:

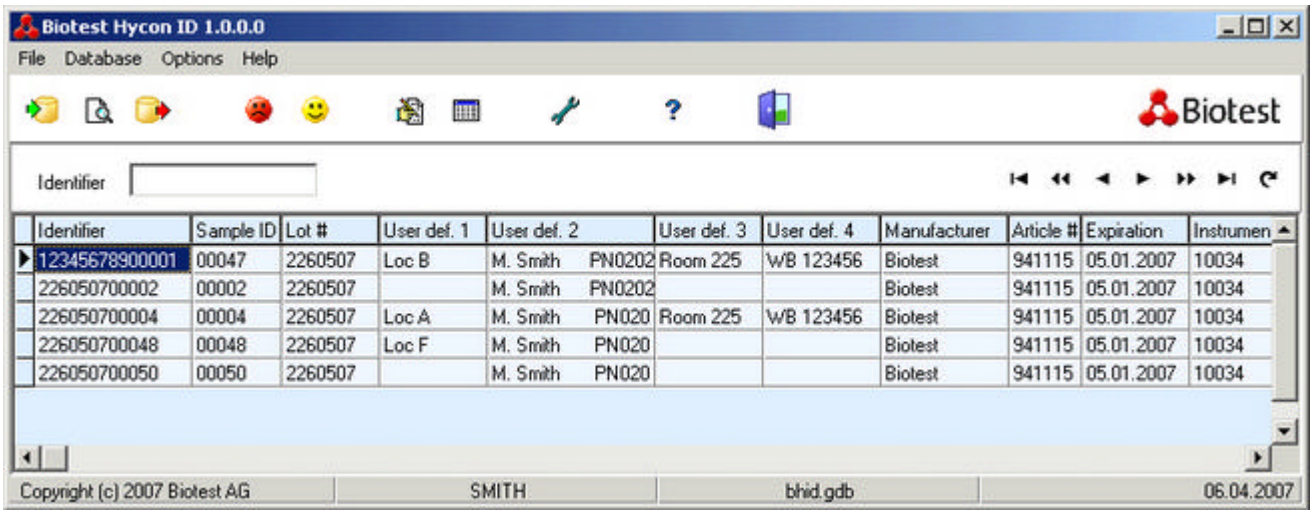


Now you can enter or scan in the identifier. After clicking on the **Results** window is called up.

Note:

If you use a scanner, the hourglass cursor appears briefly while the identifier is established based on the scanned in data.

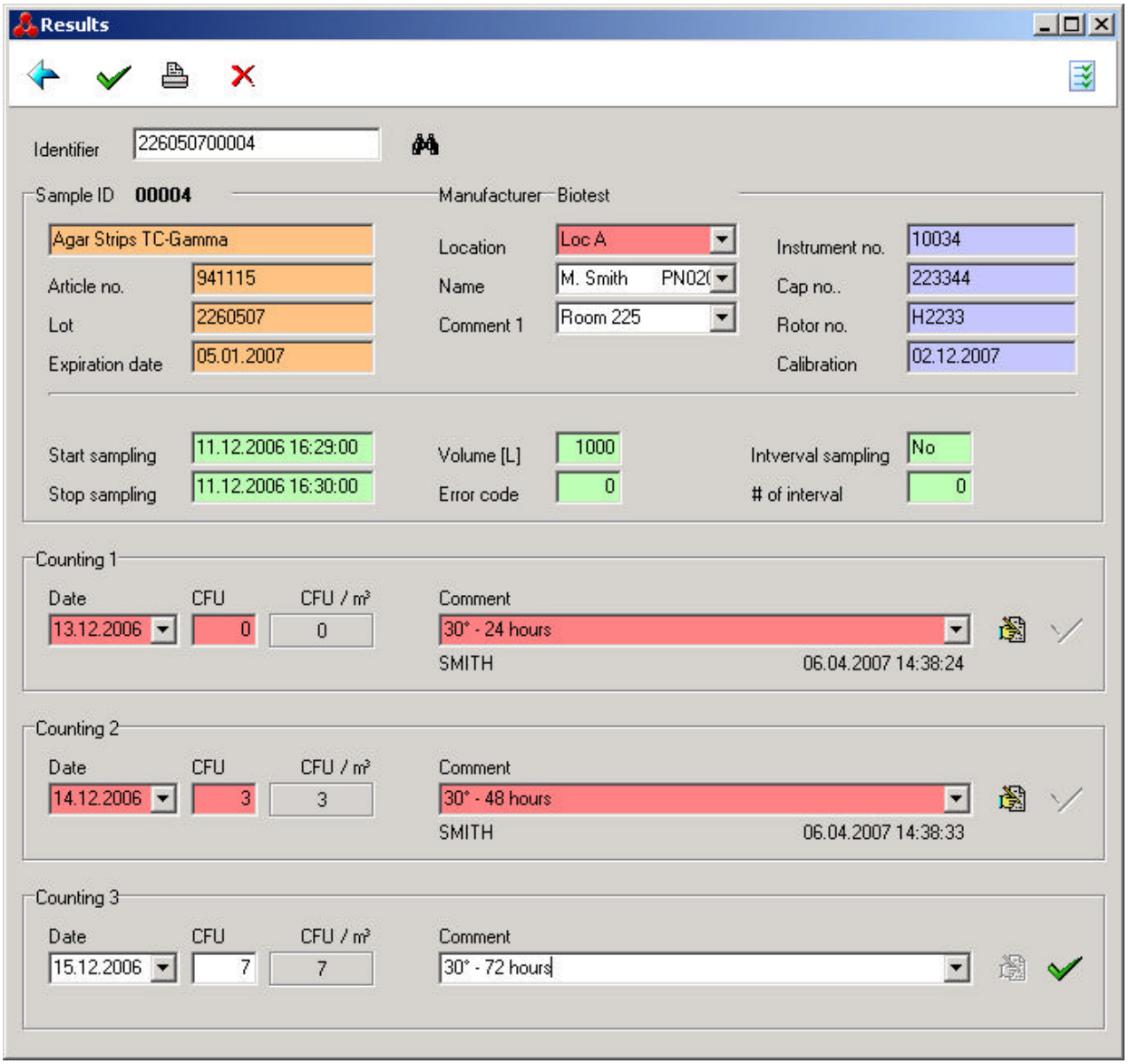
There is another way to call up the sample. Using **database - display** table or by clicking on a table appears where all samples are listed:



By double-clicking on an entry you call up the **Results** window.

3.2.2 Result of the microbiological analysis

The **Results** window is subdivided into several sections.



3.2.2.1 Buttons

Cancel - The "Results" window is closed. Any results that have not been saved are rejected

Save results - Newly entered results are saved before the "Results" window is closed.

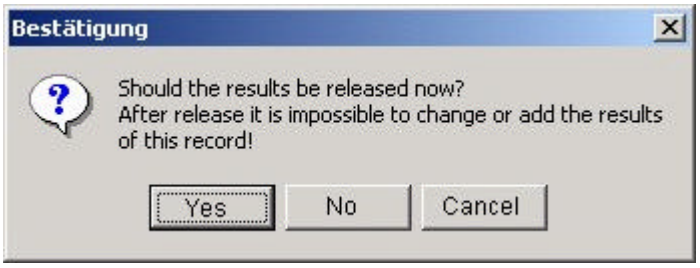
Print results - Print preview appears. See also chapter on "Output of findings"

Delete results - A warning message appears:

If you confirm this by pressing <Yes>, the whole sample is deleted not just the results of the

microbiological analysis!

Release - When the microbiological analysis is finished, the result is released. After clicking on the release button, the following message appears:


Bestätigung
Should the results be released now?
After release it is impossible to change or add the results of this record!
Yes
No
Cancel

The results will only be released after you have clicked on <Yes>. This is indicated in the top right hand corner:

The released results can neither be changed nor deleted!

Identifier and sample ID

The identifier as well as the sample ID are displayed at the top. As soon as the recording of the results for one sample is finished, you can enter or scan in the next sample in the "Identifier" field. This way, several results can be entered one after the other.

Note:

Any results that have not been saved will be lost at this moment!

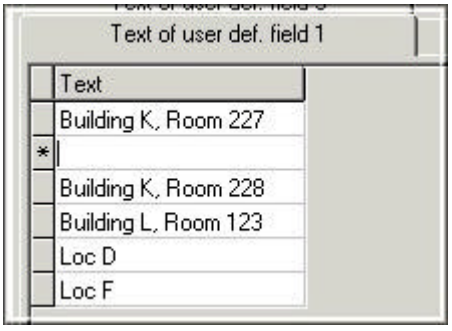
Instrument data

The fields with a coloured background are input and cannot be changed. The white fields can be used to enter details or to select information from the list.

The orange coloured fields in the upper left hand section feature information on the used test strip: a brief description of the used test strip, the item number under which the strip can be ordered from Biotest, the batch number and the expiry date of the strip.

The middle section contains up to four freely definable comments. Identifications such as "room" or "personnel ID" are entered in settings, in the "user-defined fields" property tab. This is where you determine whether the information is input by the device or entered manually. Fields that input by the device and which, therefore, cannot be changed, are coloured pink.

If, repeatedly, the same data is entered manually, this can also be specified and saved: In **settings**, in the "Help tables" property tab under the respective "user-defined field":



The blue rows of fields on the right hand side show the instrument data: instrument number, protection cap number, rotor number as well as the expiry date of the calibration.

The green fields below contain the data on the performed measurement. At a later date, the "CFU/m³" is calculated based on the volume and the result of the microbiological analysis.

Note:

The meaning of error codes is explained in the user manual of the sampler

of airborne bacteria.

3.2.2.2 Data from the microbiological analysis

For each sample, up two three results of the microbiological analysis can be recorded.

Date This is where the date of the reading is entered. If nothing is entered here, the current date appears. However, it is also possible to enter a random date.

CFU The number of the CFUs on the test strip.

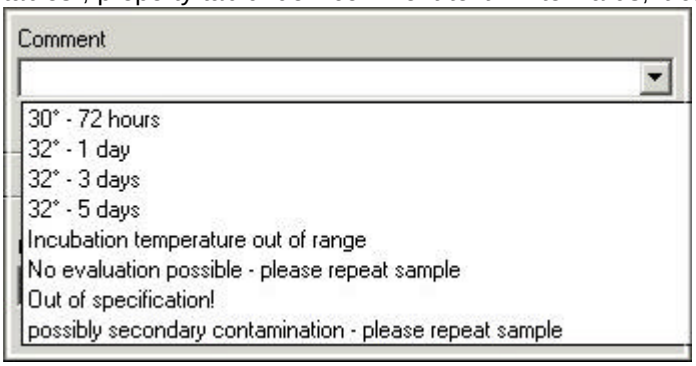
Note:

If there are more than 200 CFUs, the test strip can no longer be analysed. It is recommended to repeat the measurement with a lower sample volume.

CFU/m³ This value is calculated by the program. If the room is assigned to a clean room category, it checks whether the requirements have been adhered to. If the maximum number of bacteria has been exceeded, the following message appears:

In addition, the result is clearly marked:

Comment This is where, for example, the incubation conditions or notes on the findings can be entered. If, repeatedly, the same data is entered manually, it can be specified in **settings**, in the "Help tables", property tab under "comment text". Afterwards, it can be selected here:


Comment
30° - 72 hours
32° - 1 day
32° - 3 days
32° - 5 days
Incubation temperature out of range
No evaluation possible - please repeat sample
Out of specification!
possibly secondary contamination - please repeat sample

Save result:

By clicking on the green check mark you save the entries for this count. Now, the logged-in user and the date/time is displayed under the comments.

Edit result:

As long as the findings are not yet released, saved entries can still be changed.

Note:

Do not forget to save entries after changing them!

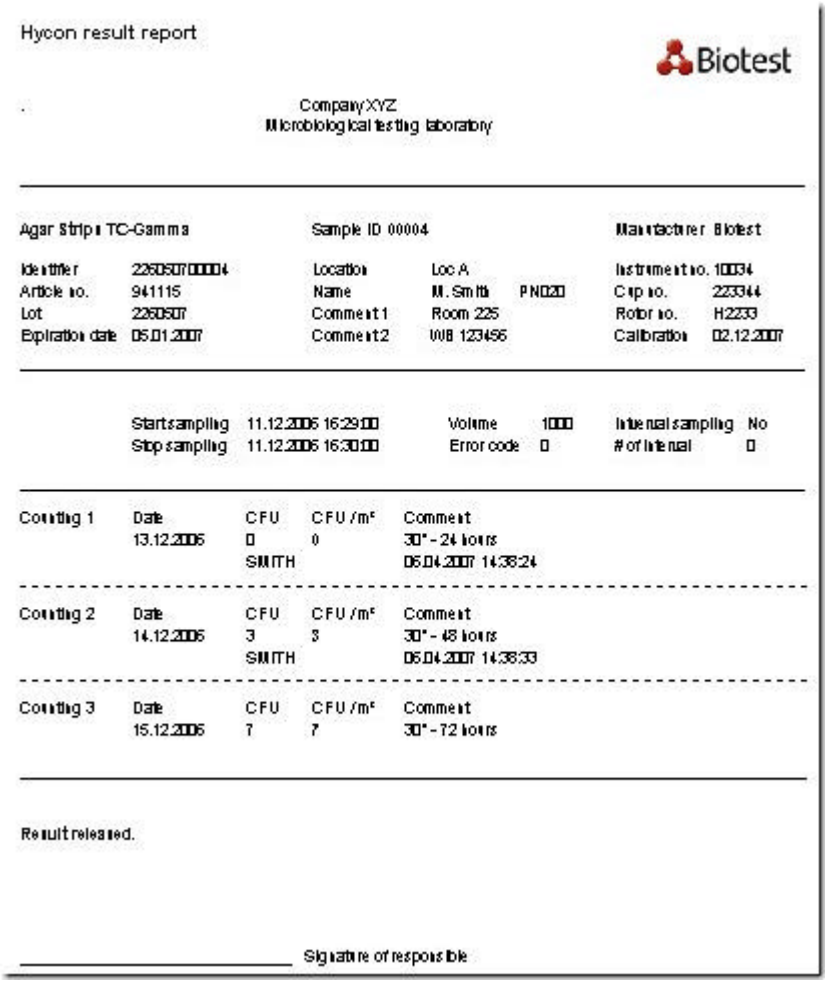
3.2.3 Output of findings

3.2.3.1 Printout

At any time, there is the option to print findings. The printout will contain all information that is displayed in the "Results" window. The printout will also feature the "Released" or "Not released" status.

The header and the footer of the printout are configured in the "Printer settings" property tab in **settings**.

After clicking on the print button, the print preview appears:


Hycon result report

Biotest

Company XYZ
Microbiological testing laboratory

Agar Strips TC-Gamma | Sample ID 00004 | Manufacturer Biotest

Identifier	2260507 00004	Location	Loc A		Instrument no.	10034	
Article no.	941115	Name	M. Smith	PN020	Cup no.	223344	
Lot	2260507	Comment 1	Room 225		Rotor no.	H2233	
Expiration date	05.01.2007	Comment 2	WB 123456		Calibration	02.12.2007	

Start sampling	11.12.2006 16:29:00	Volume	1000	Interval sampling	No
Stop sampling	11.12.2006 16:30:00	Error code	0	# of interval	0

Counting 1	Date	CFU	CFU / m³	Comment
	13.12.2006	0	0	30° - 24 hours
		SMITH		05.04.2007 14:38:24
Counting 2	Date	CFU	CFU / m³	Comment
	14.12.2006	3	3	30° - 48 hours
		SMITH		05.04.2007 14:38:33
Counting 3	Date	CFU	CFU / m³	Comment
	15.12.2006	7	7	30° - 72 hours

Result released.

Signature of responsible

In print preview, there is a choice between the following options:

Print - the printer dialog box appears where the printer can be chosen and where printing can be started.

Display of the page in print preview: whole page/width of page/size 100%

The current page size is displayed on the right.

If the findings consist of several pages, these arrows can be used to call up the different pages.

Back to the result window; no printout is performed.

3.2.3.2 Export

Currently, this option is not yet available. The plan is that future versions will offer data export.

3.2.4 Database table

The database table features a list of all samples of one database. By double clicking on one entry, the input mask for the results is displayed.

Note:

In the database table, the sample data can only be displayed not changed!

However, it is possible to sort the data by the various columns such as identifier or sample-ID. To do this, simply click on the column heading by which you want to sort the data. The column will be marked with a small triangle:

3.2.5 Archive functions

Create an archive

In order to keep databases clearly structured it makes sense to archive the released data from time to time. Archived data can be reviewed at any time.

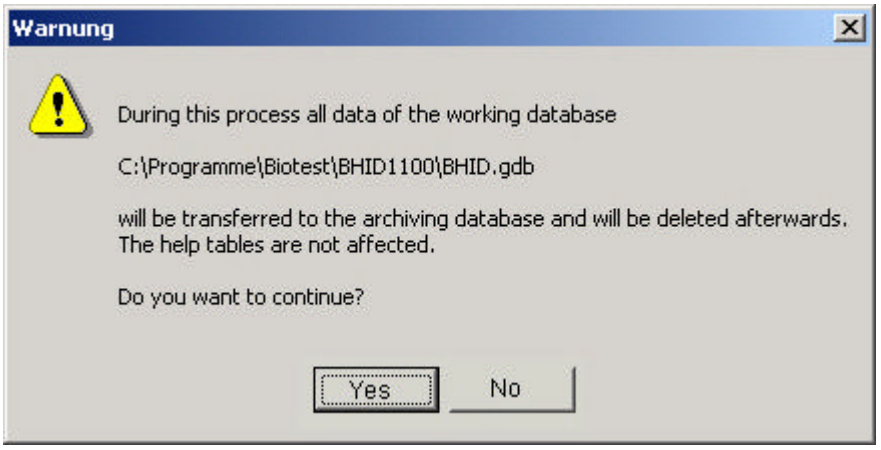
Note:

It is always the complete database that is archived! Therefore, one should ensure that all samples have been completed and released!

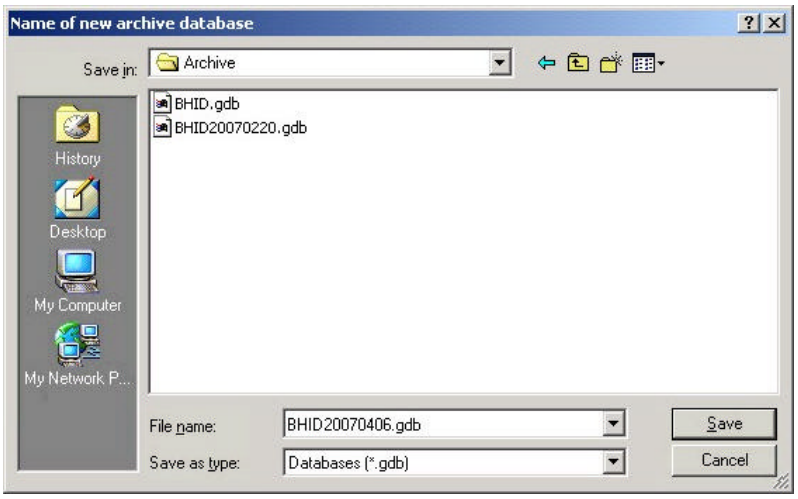
To archive data, proceed as follows:

Select Database **- Archive working database**.

→ A warning message appears:


Warnung
During this process all data of the working database
C:\Programme\Biotest\BHID1100\BHID.gdb
will be transferred to the archiving database and will be deleted afterwards.
The help tables are not affected.
Do you want to continue?
Yes
No

If you click on <Yes> the following window appears:

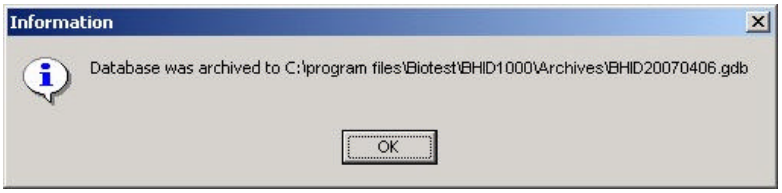


Here, you can choose where the archived data is to be saved. In this example, an additional folder called "Archives" was created under C:\Program files\Biotest\BHID1000\.

A file name in the form of BHIDyyyymmdd.gdb is proposed. This can be changed although it is important to keep the ending *.gdb.

Click on <Save> in order to create the archive.

→ After successful archiving, the following message appears:



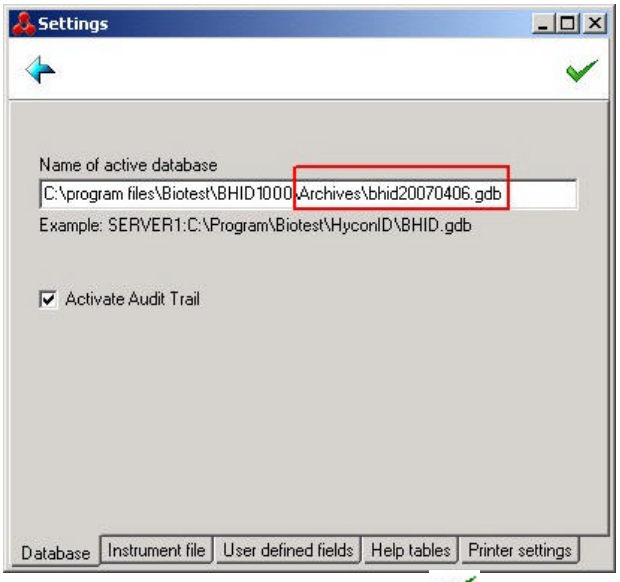
If you click on now, you will see the empty database.

Note:

All the settings remain unchanged including the help tables!

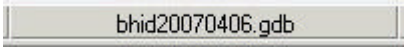
3.2.5.1 Viewing the archive

To view an archived file, it is necessary to enter the path to the archived file in the "database" property tab in **settings**:



You save the change by clicking on ✔. Now you can work with the archived data as if it was a "normal" database.

In the status bar at the bottom of the window, you can see which database is currently worked on:



3.2.5.2 Back to the current database

To do this you need to enter the path to the work database in the "database" property tab in **settings**. The standardised path is..\Program files\Biotest\BHID1000\BHID.gdb.

After clicking on ✔ the change is saved and the work database reappears.

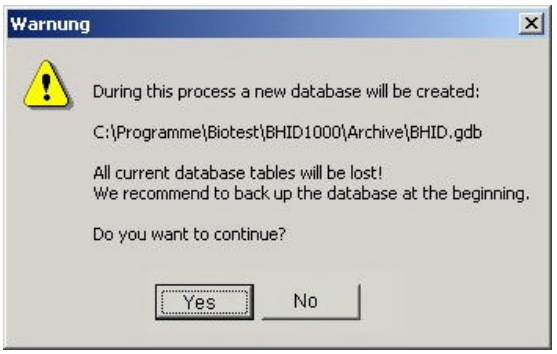
3.2.6 New working database

This option is used to create a new work database.

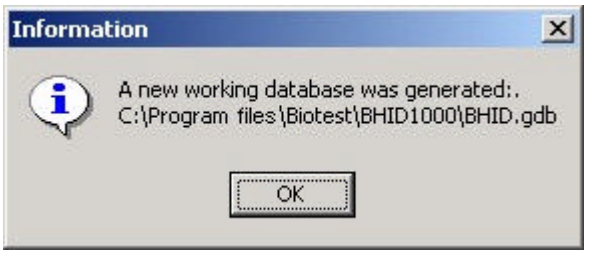
> ***Warning:***
>
> This option should only be used after consultation with the Biotest product specialist. Contrary to archiving, the database is deleted immediately. In addition, all settings in the
>
> "help tables" property tab are deleted!
>
> There, specific information has been entered for you. This needs be input again after a new database has been created.

Call-up via **database - create new working database**.

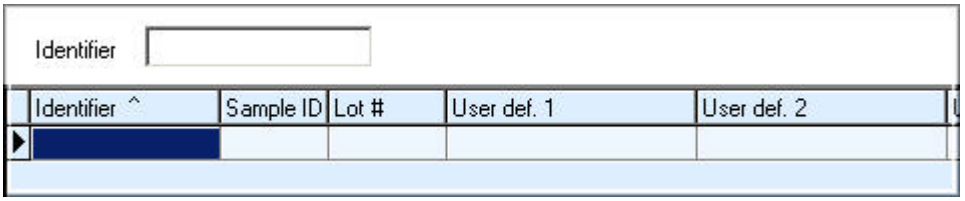
→ The following warning appears:


Warnung
During this process a new database will be created:
C:\Programme\Biotest\BHID1000\Archive\BHID.gdb
All current database tables will be lost!
We recommend to back up the database at the beginning.
Do you want to continue?
Yes
No

Click on <Yes>. The following message appears:



By clicking on you can see for yourself:



3.2.7 Online help

Press the <F1> key to get to the online help file. This will automatically display the help text matching the currently open window. If you need help for another topic, there are several methods to find it quickly:

- Use the index on the left side; it's identical with the printed manual.
- Select "Index" or "Keywords" to enter the topic for which you need help. This will display all the topics containing this keyword.
- Use the arrow keys to scroll back and forth. This is quite useful when you are trying to familiarize yourself with a complex topic such as, for example, settings.

3.2.8 Exit program

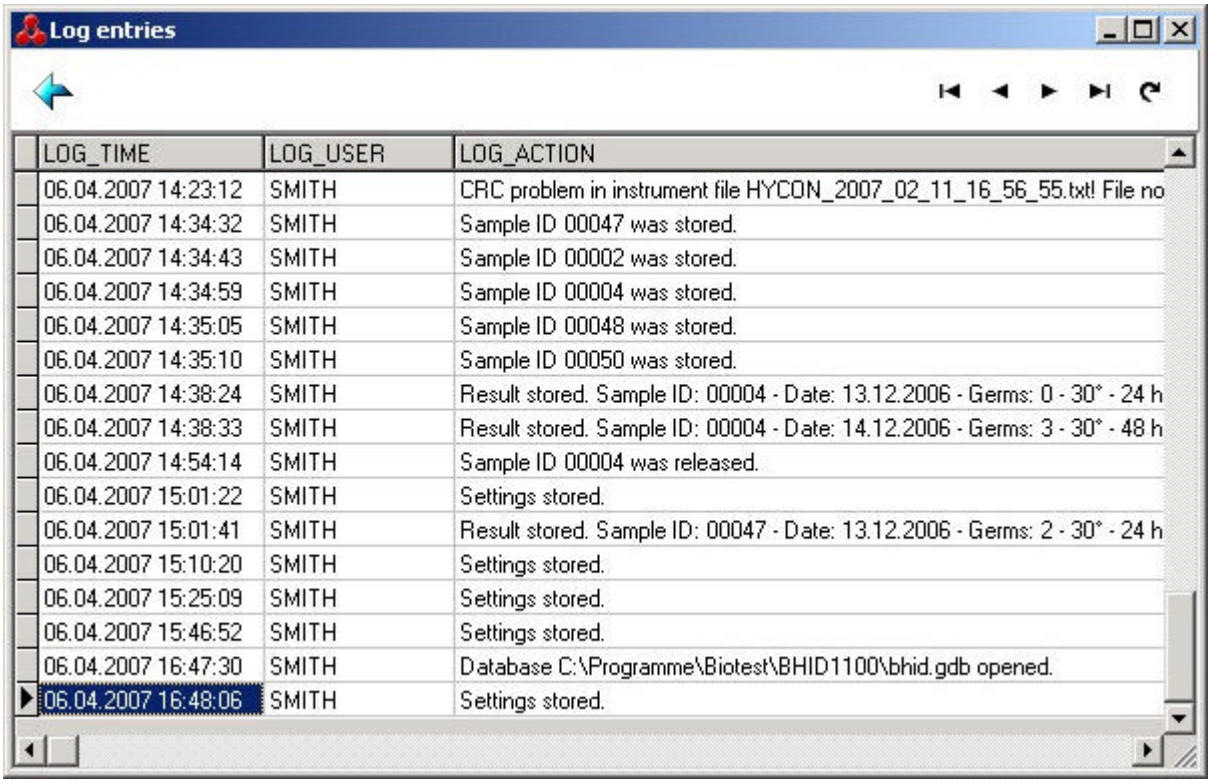
- You can close the program by using the ☒ at the top right corner (as in any Windows application)
- by selecting **File - Close**
- or directly by using the button

4 Annex

4.1 Log file

If in the "Database" property tab under **settings** the "Activate audit trail" option is activated, a log file compliant with 21 CFR Part 11 is being kept:

This is where all events are recorded. By calling up **File - display logged entries** or by clicking on you can view this log file:



LOG_TIME	LOG_USER	LOG_ACTION
06.04.2007 14:23:12	SMITH	CRC problem in instrument file HYCON_2007_02_11_16_56_55.txt! File no
06.04.2007 14:34:32	SMITH	Sample ID 00047 was stored.
06.04.2007 14:34:43	SMITH	Sample ID 00002 was stored.
06.04.2007 14:34:59	SMITH	Sample ID 00004 was stored.
06.04.2007 14:35:05	SMITH	Sample ID 00048 was stored.
06.04.2007 14:35:10	SMITH	Sample ID 00050 was stored.
06.04.2007 14:38:24	SMITH	Result stored. Sample ID: 00004 - Date: 13.12.2006 - Germs: 0 - 30° - 24 h
06.04.2007 14:38:33	SMITH	Result stored. Sample ID: 00004 - Date: 14.12.2006 - Germs: 3 - 30° - 48 h
06.04.2007 14:54:14	SMITH	Sample ID 00004 was released.
06.04.2007 15:01:22	SMITH	Settings stored.
06.04.2007 15:01:41	SMITH	Result stored. Sample ID: 00047 - Date: 13.12.2006 - Germs: 2 - 30° - 24 h
06.04.2007 15:10:20	SMITH	Settings stored.
06.04.2007 15:25:09	SMITH	Settings stored.
06.04.2007 15:46:52	SMITH	Settings stored.
06.04.2007 16:47:30	SMITH	Database C:\Programme\Biotest\BHID1100\bhid.gdb opened.
06.04.2007 16:48:06	SMITH	Settings stored.

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